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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,042	11/14/2000	Lixiao Wang	S63.2-9213	9167

490 7590 12/27/2005

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

MCCORKLE, MELISSA A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/712,042	<b>Applicant(s)</b> WANG ET AL.	
	<b>Examiner</b> Melissa A. McCorkle	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19-45 is/are pending in the application.
- 4a) Of the above claim(s) 21-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19, 20 and 30-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 20, 31, 32, and 34-45 are objected to because of the following informalities: Claims 20, 34, 36, 37 and 45 do not further limit the parent claim, since the limitations are the same as recited as in claim 19. Regarding claims 31, 32, 39, 40, 42, the term "nominal diameter" has not been defined and is therefor indefinite. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 19, 20, 33, 34, 35, 36, 37, 41, and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Hamlin (5,270,086).

Regarding claims 19, 34, 35, 36, 37, and 45, Hamlin discloses a balloon for a medical device (fig 4) formed from a length of tubing by radial expansion of the tubing under pressure, the polymer material comprising a melt blend product [col 2 lines 4-11] of at least two thermoplastic polymers [col 1 line 65 – col 2 line 11], a first of said polymers

Art Unit: 3763

being an engineering resin [col 2 lines 30-68] having a flexural modulus of 240,000 psi [it is inherent that an engineering resin, such as ABS polymers, is capable of having a flexural modulus of 240,000 psi or greater or about 300,000 psi] and a second of said polymers being a block copolymer elastomer [col 2 lines 30-68] having a flexural modulus of about 150,000 psi or less [it is inherent that a block copolymer elastomer is capable of having a flexural modulus of 150,000 psi or less and is well within the skill of the ordinary artisan], the block copolymer including at least one block which is structurally similar to the engineering resin, wherein the first and second polymers are a pair selected from the group consisting of engineering polyurethane resins and polyurethane elastomers; aromatic polyesters or copolyesters and aromatic polyester-polyether block copolymers; aromatic polyesters and polyurethane-polyester block copolymers; and polycarbonates and polycarbonate urethane elastomers [col 2 line 31 – col 3 line 8; Hamlin discloses that many combinations from the materials disclosed can be made depending on the desired characteristics such as strength, expansion pressure, etc, as well as distinctly discloses the several of the combinations above].

1. Regarding claim 20, Hamlin discloses the balloon as stated above, wherein the first and second polymers are engineering polyurethane resins and polyurethane elastomers, respectively [col 2 line 31 – col 3 line 8; Hamlin discloses that many combinations from the materials disclosed can be made depending on the desired characteristics such as strength, expansion pressure, etc, as well as distinctly discloses the several of the combinations above].

2. Regarding claims 33 and 41, Hamlin discloses a dilation catheter [fig 5] having an elongated tubular body, a balloon mounted on a distal end thereof and means for inflating the balloon, wherein the balloon is as stated above.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 30, 31, 32, 38, 39, and 40, 42, 43, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamlin (5,270,086). Hamlin discloses all of the invention as stated above, however Hamlin does not expressly state that a wall strength greater than 20,000 psi or the nominal diameter of a balloon being between 1.5 mm and 4.4 mm. However, in Applicant's specification he states that "Tensile wall strengths are commonly 20,000-50,000 psi" [page 2] and that commercially available balloons have nominal diameters in the range of 1.5-4.5mm [page 2]. Therefore, at the time the invention was made, it would have been obvious to make the catheter of Hamlin to the specifications since these specifications are generally used when making a catheter. Furthermore, one of ordinary skill in the art would expect Hamlin's catheter balloon to perform equally well with a catheter of these dimensions because they perform the same function. This is considered a mere design consideration which fails to patentably distinguish over Hamlin. Hamlin's catheter balloon is capable of having a burst

Art Unit: 3763

pressure of at least 12 atm or about 16 atm (well over 7 atm [col 5 line 28]) when the materials are combined as above.

### ***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pinchuk et al (4,906,244) discloses balloons for medical devices and fabrication thereof; Jackowski et al (4,938,676) discloses an apparatus for manufacturing balloons for medical devices; Lombardi et al (5,254,090) discloses a balloon catheter having a dual layer inner member; Chen et al (5,554,120) discloses polymer blends for use in making medical devices including catheters and balloons for dilatation catheters; Hamilton et al (6,086,556) discloses medical device balloons containing thermoplastic elastomers; Ferrera et al (6,242,063) discloses balloons made from liquid crystal polymer blends.

### ***Contacts***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MAM  
12/21/2005



NICHOLAS J. HUGHES  
SUPERVISOR, PATENT EXAMINER  
TECHNOLOGY CENTER 3700